

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Richman *et al.*

Application No.: TO BE ASSIGNED

Group Art Unit: TO BE ASSIGNED

Filed: Herewith

Examiner: TO BE ASSIGNED

For: METHODS AND  
COMPOSITIONS FOR  
DIAGNOSIS AND  
TREATMENT OF IRON  
OVERLOAD DISEASES AND  
IRON DEFICIENCY  
DISEASES

Attorney Docket No.: 8907-098-999

**PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments. Applicants include herewith *Appendix A*, comprising a copy of the claims as pending after entry of the instant Amendment.

**AMENDMENT**

**In The Specification:**

Please amend the Specification as follows:

Please delete the paragraph beginning at page 1, line 7, and replace it with the following paragraph:

The present application is a divisional application of co-pending United States application serial no. 09/094,964, filed June 12, 1998, incorporated herein by reference in its

entirety, which is a continuation-in-part of United States application serial no. 08/876,010, filed June 13, 1997, now abandoned, which is incorporated herein by reference in its entirety.

**In The Claims:**

After canceling Claims 1-6 without prejudice as directed in the accompanying Divisional Patent Application Transmittal, please add new Claims 7-9:

7. (New) A composition for treating an iron overload disease comprising a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:1 and a full length, wild-type human  $\beta_2m$ .

8. (New) A composition for treating an iron deficiency disease comprising a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:2 and a full length, wild-type human  $\beta_2m$ .

9. (New) A composition for treating an iron deficiency disease comprising administering to a patient a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:3 and a full length, wild-type human  $\beta_2m$ .

### REMARKS

Applicants have amended the Specification to indicate that the instant application is a divisional application of co-pending United States application serial no. 09/094,964. This amendment is made pursuant to 37 C.F.R. § 1.115. Accordingly, Applicants respectfully request that the amendment be entered.

With this amendment Claims 7-9 are pending. The claims have been amended, without prejudice, for the purpose of more clearly defining what Applicants regard as the invention.

Claims 1-6 have been canceled, without prejudice, by the accompanying Preliminary Amendment. Applicants expressly reserve the right to prosecute the subject matter of the canceled claims in one or more timely filed divisional, continuation or continuation-in-part applications.


CONCLUSION

In view of the above amendment and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

No fee is believed due in connection with this submission. However, the Commissioner is authorized to charge any required fee or credit any overpayment to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Date March 4, 2002

Respectfully submitted,



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**Appendix A**  
**Claims As Pending After Entry Of The Instant Amendments**

7. (New) A composition for treating an iron overload disease comprising a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:1 and a full length, wild-type human  $\beta_2m$ .
8. (New) A composition for treating an iron deficiency disease comprising a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:2 and a full length, wild-type human  $\beta_2m$ .
9. (New) A composition for treating an iron deficiency disease comprising administering to a patient a therapeutically effective amount of a soluble complex comprising an HFE polypeptide according to SEQ ID NO:3 and a full length, wild-type human  $\beta_2m$ .